



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,267	07/24/2000	ANUSCHIRWAN PEYMAN	02481.1669	2235

5487 7590 08/10/2004

ROSS J. OEHLER
AVENTIS PHARMACEUTICALS INC.
ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

914.

Office Action Summary

Application No.

09/554,267

Applicant(s)

PEYMAN ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-34 and 41-63 is/are pending in the application.
- 4a) Of the above claim(s) 55-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-34, 41-44 and 63 is/are rejected.
- 7) ☒ Claim(s) 45-54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 5-19-04.

Claims 26-34, 41-63 are pending in the instant application.

Election/Restrictions

This application contains claims 55-62, SEQ ID Nos: 12-20 (in claim 26), SEQ ID Nos: 31-39 (in claim 32) and SEQ ID Nos: 50-58 (in claim 33), drawn to an invention nonelected with traverse in the reply filed on 9-22-03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejection not repeated in this Office action is hereby withdrawn.

Maintained Rejections

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Denner et al in view of Baracchini et al and Friesen et al for the reasons of record set forth in the Office action mailed 12-19-03.

Applicant's arguments filed 5-19-04 have been fully considered but they are not persuasive. Applicants argue that Denner does not render the instant invention obvious because Denner does not require a specific pattern of modifications to the internucleoside bridges as set forth in the instant invention. Applicants also argue that

Denner teaches that oligonucleotides of at least 18 nucleotides can be used as antisense against the target tenascin gene, and the instant invention contains the limitation of 17 or fewer nucleotides in length.

Contrary to Applicants' assertions, the instant invention of claim 63 does not limit antisense length to 17 or fewer nucleotides. Rather, the claimed invention is drawn to an in vitro method of inhibiting tenascin comprising the administration of an antisense oligonucleotide *comprising* any of SEQ ID NO:21-30. The minimum lengths of the claimed oligonucleotides in claim 63 are those lengths of the antisense oligonucleotides themselves (e.g. 17 bases for SEQ ID NO: 21...) Denner teaches the vitro inhibition of tenascin expression comprising the administration of oligonucleotides *comprising* (e.g. the length of the oligonucleotide itself or this oligonucleotide sequence within a larger sequence) or *consisting of* (e.g. the exact length of the claimed sequence) SEQ ID Nos: 22, 23, 24, 26, and their administration to target cells in vitro, which oligonucleotides optionally further comprise phosphorothioate internucleotide linkages. In this regard, Denner teaches the nucleotide sequences of SEQ ID Nos. 22, 23, 24 and 26 as claimed in the instant invention of claim 63.

Applicants are correct that the prior art does not anticipate the particular configurations of the modifications set forth in the antisense oligonucleotides of 22, 23, 24 and 26, but Denner does teach the incorporation of these modifications into antisense, which particular configurations of the instant invention are a design choice for a given oligonucleotide. Absent evidence to the contrary, the oligonucleotide sequences previously disclosed by Denner, and the internucleotide modifications

generally taught by Baracchini and routinely used for enhancing oligonucleotide stability in the art of molecular biology, would effectively inhibit expression of the tenascin target gene in vitro and render the instant invention of claim 63 obvious. Therefore, the incorporation of modified internucleotide linkages into the SEQ ID Nos: 22, 23, 24 and 26, as taught previously by Baracchini, would have been obvious to one of ordinary skill in the art.

Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-34, 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites an oligonucleotide comprising a sequence selected from SEQ ID Nos: 2-11, wherein the oligonucleotide has a length of 7-17 nucleotides. It is unclear how the limitations of the claimed invention (i.e. oligonucleotides of a length of 7 nucleotides describing oligonucleotides of lengths of at least 12 nucleotides and at most 17 nucleotides) can be reconciled. These limitations are contradictory and both cannot be fulfilled. In the interest of compact prosecution, the claimed invention is interpreted to recite an oligonucleotide comprising a sequence selected from SEQ ID Nos: 2-11, wherein the oligonucleotide has a maximum length of 17 nucleotides, and a minimum

length of the corresponding SEQ ID (i.e. a minimum of 17 nucleotides for SEQ ID Nos: 2, 3, 6; a minimum of 16 nucleotides for SEQ ID Nos: 8 and 11; a minimum of 15 nucleotides for SEQ ID Nos: 9 and 10; a minimum of 14 nucleotides for SEQ ID Nos: 4 and 5; and a minimum of 12 nucleotides for SEQ ID NO: 7). This interpretation is consistent with the term *comprising*, as stated in line 2 of claim 26. Amending line 6 of claim 26 from “a length of 7 to 17 nucleotide units” to –a maximum length of 17 nucleotide units—would be remedial.

Allowable Subject Matter

Claims 45-54 are objected to as depending from a rejected claim. These claims are free of the prior art searched and of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

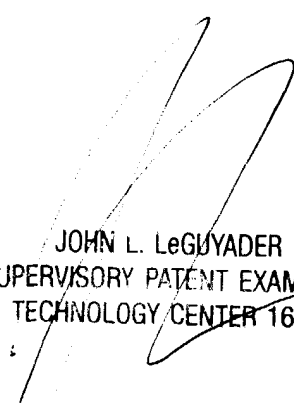
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ
7-29-04



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600